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Dated: 3/13/06 Signature: *Ginny Blundell*  
(Ginny Blundell)

Docket No.: HYDR-P01-005  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Li et al.

Application No.: 10/509472

Confirmation No.: 6718

Filed: September 21, 2005

Art Unit: 1636

For: ELASTIN PREVENTS OCCLUSION OF  
BODY VESSELS BY VASCULAR SMOOTH  
MUSCLE CELLS

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application as required by 37 CFR 1.98(a)(2)(i), amended October 2004, as the U.S. Patent and Trademark Office has waived this requirement for all U.S. patent applications. Applicant submits herewith copies of foreign and non-patents in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information

as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. HYDR-P01-005.

Dated: 3/13/06

Respectfully submitted,

By 

Melissa S. Rones, Ph.D.

Registration No.: 54,408

ROPES & GRAY LLP

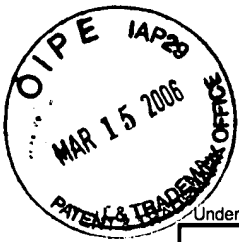
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Application No. (if known): 10/509472

Attorney Docket No.: HYDR-P01-005

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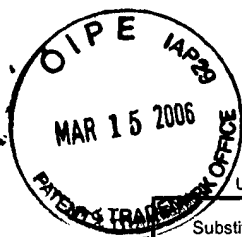
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References (BA-BS, CA-CM3)



PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

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<p>Substitute for form 1449A/B/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(Use as many sheets as necessary)</p>				<b>Complete if Known</b>	
				Application Number	10/509472
				Filing Date	September 21, 2005
				First Named Inventor	Dean Y. Li
				Art Unit	1636
				Examiner Name	Not Yet Assigned
Sheet	1	of	6	Attorney Docket Number	HYDR-P01-005

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> ( if known)			
	AA*	4,323,358	04-06-1982	Lentz et al.	
	AB*	4,352,887	10-05-1982	Reid et al.	
	AC*	4,553,974	11-19-1985	Dewanjee	
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	AE*	4,877,599	10-31-1989	Lees	
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	AJ1*	5,990,379	11-23-1999	Gregory	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BA	JP-59112909	06-29-1984			
	BB	JP-59112951	06-29-1984			
	BC	WO-90/07936	07-26-1990	Chiron Corporation		
	BD	WO-92/19195	11-12-1992	Brown University Research Foundation		
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				Art Unit	1636
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Sheet	2	of	6	Attorney Docket Number	HYDR-P01-005

	BE	WO-92/22309	12-23-1992	Imperial Chemical Industries, PLC		
	BF	WO-94/25503	11-10-1994	Cytotherapeutics, Inc.		
	BG	WO-95/01203	01-12-1995	Cytotherapeutics, Inc.		
	BH	WO-95/05452	02-23-1995	Cytotherapeutics, Inc.		
	BI	WO-96/02286	02-01-1996	Cytotherapeutics, Inc.		
	BJ	WO-96/02646	02-01-1996	Cytotherapeutics, Inc.		
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	BL	WO-96/40959	12-19-1996	Cytotherapeutics, Inc.		
	BM	WO-97/12635	04-10-1997	Cytotherapeutics, Inc.		
	BN	WO-97/34998	09-25-1997	Human Genome Sciences, Inc.		
	BO	WO-98/01740	01-15-1998	University of Utah Research Foundation		
	BP	WO-98/05685	02-12-1998	Protein Specialities, LTD.		
	BQ	WO-99/03886	01-28-1999	The University of Sydney		
	BR	WO-99/45941	09-16-1999	MRS, LLC		
	BS	WO-99/53943	10-28-1999	Angio-Genix, Incorporated		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. \* Applicant's unique citation designation number (optional). \* See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. \* Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \* For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \* Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \* Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	CA	Adams et al., "Regulation of development and differentiation by the extracellular matrix," Development, 117:1183-1198, (1993).		
	CB	American Heart Association, <i>Heart and Stroke Facts: 1996 Statistical Supplement</i> (American Heart Association, Dallas, TX) (1996).		
	CC	Anders et al., "MURINE Models of Renal Disease: Possibilities and Problems in Studies Using Mutant Mice," Exp. Nephrol., 8:181-193, (2000).		
	CD	Beck et al., "Vascular development: cellular and molecular regulation," FASEB, 11:365-373, (1997).		
	CE	Bloom, W. and Fawcett, D., "A Textbook of Histology", 10 Ed., pages 398-402 (Saunders, Philadelphia) (1975)		
	CF	Boyle et al., "Endothelium-independent Vasoconstricting and Vasodilating Actions of Halothane on Rat Mesenteric Resistance Blood Vessels," Anesthesiology, 82(1):221-235, (1995).		
	CG	Bradley, et al., "Modifying the Mouse: Design and Desire," Bio Tech., 10:534-539, (1992).		
	CH	Burn et al., "Developmental genetics of the heart," Curr. Opin. In Genetics and Development, 6:322-325, (1996).		
	CI	Carmeliet et al., "Abnormal blood vessel development and lethality in embryos lacking a single VEGF allele," Nature, 380 (6573):435-439, (1996).		
	CJ	Cowan, K. et al., "Serine Elastase and Matrix Metalloproteinase (MMP) Inhibition Induced Pulmonary Artery (PA) Smooth Muscle Cell (SMC) Apoptosis Leading to Regression of Vascular Hypertrophy" Molecular Biology of the Cell 8 (Supp.) page 287A (1997)		
Examiner Signature				Date Considered

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Sheet	3	of	6		

CK	Curran et al., "The Elastin Gene Is Disrupted by a Translocation Associated with Supravalvular Aortic Stenosis," Cell, 73:159-168, (1993).	
CL	Davis, Elaine, "Elastic Lamina Growth in the Developing Mouse Aorta," Journal of Histochemistry and Cytochemistry, 43(11):1115-1123, (1995).	
CM	Deng et al., "Location of crossovers during gene targeting with insertion and replacement vectors," Mol. Cell. Biol. 13(4):2134-2140, (1993) (Abstract)	
CN	Dietz et al., "Mutations in the human gene for fibrillin-1 ( <i>FBN1</i> ) in the Marfan syndrome and related disorders," Human Molecular Genetics, 4:1799-1809 (1995).	
CO	Eck et al., "Gene-Based Therapy", Goodman & Gilman's The Pharmacological Basis of Therapeutics, McGraw-Hill, New York, pages 77-101 (1996)	
CP	Ewart et al., "A human vascular disorder, supravalvular aortic stenosis, maps to chromosome 7," Proc. Natl. Acad. Sci., 90:3226-3230, (1993).	
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CT	Ferrara et al., "Heterozygous embryonic lethality induced by targeted inactivation of the VEGF gene," Nature, 380:439-442 (1996).	
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CX	Gardner et al., "Deletion of Integrin $\alpha 1$ by Homologous Recombination Permits Normal Murine Development but Gives Rise to a Specific Deficit in Cell Adhesion," Dev. Biol. 175:301-313, (1996).	
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CZ	Gibbons et al., "Molecular Therapies for Vascular Diseases," Science, 272:689-693, (1996).	
CA1	Glagov, et al., "Compensatory enlargement of human atherosclerotic coronary arteries," New England Jour. of Med., 316:1371-1375, (1987).	
CB1	Glukhova et al., "Phenotypic changes of Human Aortic Smooth Muscle Cells During Development and in the Adult Vessel", American Journal of Physiology, 261, pages 78-80 (1991)	
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CD1	Hanahan, Douglas, "Signaling Vascular Morphogenesis and Maintenance," Science, 277:48-50, (1997).	
CE1	Houdebine, Louis-Marie, "Production of pharmaceutical proteins from transgenic animals," Journal of Biotechnology, 34:269-287, (1994).	
CF1	Hynes, Richard O., "Genetic analyses of cell-matrix interactions in development," Curr. Opin. Genet. Dev., 4:569-574 (1994).	
CG1	Hynes, Richard, "Integrins: Versatility, Modulation, and Signaling in Cell Adhesion," Cell, 69:11-25, (1992).	
CH1	Ito, et al., "Inhibitory effect of type 1 collagen gel containing $\alpha$ -elastin on proliferation and migration of vascular smooth muscle and endothelial cells," Cardiovascular Surgery, 5(2):176-183, (1997).	
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Sheet	4	of	6	Attorney Docket Number	HYDR-P01-005

CI1	Katoh et al., "Growth and Differentiation of Smooth Muscle Cells During Vascular Development," Trends Cardiovasc. Med., 6(3):100-106 (1996).
CJ1	Kaye et al., "A single amino acid substitution results in a retinoblastoma protein defective in phosphorylation and oncoprotein binding," Proc. Natl. Acad. Sci., 87:6922-6926, (1990).
CK1	Keating, M.T., "Genetic Approaches to Cardiovascular Disease," Circulation, 92:142-147 (1995).
CL1	Keating, Mark, "Elastin and Vascular Disease," Trends in Cardiovascular Medicine, 4(4):165-169, (1994).
CM1	Keating, Mark, "On the trail of genetic culprits in Williams syndrome," Cardiovasc. Res., 36:134-137, (1997).
CN1	Koyama et al., "Fibrillar Collagen Inhibits Arterial Smooth Muscle Proliferation through Regulation of Cdk2 Inhibitors," Cell, 87:1069-1078 (1996).
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CS1	Lindahl et al., "Pericyte Loss and Microaneurysm Formation in PDGF-B-Deficient Mice," Science, 277:242-245 (1997).
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CU1	Machii et al., "Morphologic Features of the Normal Aortic Arch in Neonates, Infants, and Children Pertinent to Growth," Ann Thorac Surg, 64:511-515 (1997).
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CZ1	O'Connor et al., "Supravalvular Aortic Stenosis," Arch. Pathol. Lab Med., 109:179-185 (1985).
CA2	Ooyama et al., "Substratum-Bound Elastin Peptide Inhibits Aortic Smooth Muscle Cell Migration in Vitro," Arteriosclerosis, 7(6):593-598 (1987).
CB2	Owens, Gary, "Regulation of Differentiation of Vascular Smooth Muscle Cells," Physiol. Rev., 75(3):487-517 (1995).
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CD2	Parks et al., "Elastin," Advances in Molecular and Cell Biology, 6:133-181 (1993).
CE2	Perou, Maurice L., "Congenital Supravalvular Aortic Stenosis," Arch. Pathol., 71:113-126 (1961).
CF2	Perrin et al., "Developmental Regulation of Elastin Gene Expression," Crit. Rev. Eukaryot. Gene Exp., 7(1&2):1-10, (1997).
CG2	Prosser et al., "Regional Heterogeneity of Elastin and Collagen Gene Expression in Intralobar Arteries in Response to Hypoxic Pulmonary Hypertension as Demonstrated by <i>In Situ</i> Hybridization," Amer. J. Pathol., 135(6):1073-1088 (1989).

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CH2	Pursel et al., "Expression and performance in transgenic pigs," J. Reprod. Fert., Suppl., 40:235-245 (1990).	
CI2	Rabinovitch, Marlene, "Cell-Extracellular Matrix Interactions in the Ductus Arteriosus and Perinatal Pulmonary Circulation," Seminars in Perinatology, 20(6):531-541, (1996).	
CJ2	Raju et al., "Primary Structures of Bovine Elastin a, b, and c Deduced from the Sequences of cDNA Clones," Journal of Biological Chemistry, 262(12):5755-5762, (1987).	
CK2	Reitamo et al., "Interleukin 10 up-regulates elastin gene expression in vivo and in vitro at the transcriptional level," Biochem. Jour., 302:331-333, (1994).	
CL2	Ross, Russell, "The pathogenesis of atherosclerosis: a perspective for the 1990s," Nature, 362:801-809 (1993).	
CM2	Rudinger, "Characteristics of the Amino Acids as Components of a Peptide Hormone Sequence, Peptide Hormones, pages 1-7 (1976)	
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CQ2	Schwartz et al., "Developmental Mechanisms Underlying Pathology of Arteries," Physiol. Rev., 70(4):1177-1209 (1990).	
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CS2	Seamark, R.F., "Progress and Emerging Problems in Livestock Transgenesis: a Summary Perspective," Reprod. Fertil. Dev., 6:653-657, (1994).	
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CU2	Senior et al., "Chemotactic Activity of Elastin-derived Peptides," J. Clin. Inv., 66:859-862, (1980).	
CV2	Senior et al., "Val-Gly-Val-Ala-Pro-Gly, a Repeating Peptide in Elastin, Is Chemotactic for Fibroblasts and Monocytes," The Journal of Cell Biology, 99:870-874 (1984).	
CW2	Shalaby et al., "Failure of blood-island formation and vasculogenesis in Flk-1-deficient mice," Nature, 376:62-66 (1995).	
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CY2	Suri et al., "Requisite Role of Angiopoietin-1, a Ligand for the TIE2 Receptor, during Embryonic Angiogenesis," Cell, 87:1171-1180 (1996).	
CZ2	Tajima et al., "Modulation by elastin peptide VGVAPG of cell proliferation and elastin expression in human skin fibroblasts," Archives of Dermatological Research, 289(8):489-492, (1997).	
CA3	Tajima, Shingo, "Correlation of Elastin Expression and Vascular Smooth Muscle Cell Proliferation <i>In Vitro</i> ," Extracellular Matrix-Cell Interactions: Molecules to Diseases (Japan Scientific Societies Press) Pages 109-121 (1998).	
CB3	Tassabehji et al., "An elastin gene mutation producing abnormal tropoelastin and abnormal elastic fibres in a patient with autosomal dominant cutis laxa," Human Molecular Genetics, 7(6):1021-1028, (1998).	
CC3	Tassabehji et al., "Elastin: genomic structure and point mutations in patients with supravalvular aortic stenosis," Human Molecular Genetics, 6(7):1029-1036, (1997).	
CD3	Terpin et al., "A biophysical and histological analysis of factors that lead to aortic rupture in normal and lathyrus turkeys," Can. J. Physiol. Pharmacol., 65:395-400 (1987).	
CE3	Thomas et al., "Targeted disruption of the murine <i>int-1</i> proto-oncogene resulting in severe	
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		abnormalities in midbrain and cerebellar development," Nature, 346:847-850 (1990).	
	CF3	Thompson, Robert W., "Basic science of abdominal aortic aneurysms: emerging therapeutic strategies for an unresolved clinical problem," Curr. Opin. Cardiol., 11:504-518 (1998).	
	CG3	Wolinsky et al., "A Lamellar Unit of Aortic Medial Structure and Function in Mammals," Circ. Res., 20:99-111 (1967).	
	CH3	Wu et al., "Delineation of the common critical region in Williams syndrome and clinical correlation of growth, heart defects, ethnicity, and parental origin," Am. J. Med. Genet., 78(1):82-89, (1998).	
	CI3	Wu et al., "Methods in Gene Biotechnology," Chapter 17, pages 339-365.	
	CJ3	Wydner et al., "Use of an Intron Length Polymorphism to Localize the Tropoelastin Gene to Mouse Chromosome 5 in a Region of Linkage Conservation with Human Chromosome 7," Genomics, (23):125-131, (1994).	
	CK3	Yamamoto et al., "Increase in Elastin Gene Expression and Protein Synthesis in Arterial Smooth Muscle Cells Derived From Patients with Moyamoya Disease," Stroke, 28(9):1733-1738, (1997).	
	CL3	Yang et al., "Embryonic mesodermal defects in $\alpha 5$ integrin-deficient mice," Development, 119:1093-1105 (1993).	
	CM3	Zheng et al., "Vitronectin is not essential for normal mammalian development and fertility," Proc. Natl. Acad. Sci. USA, 92:12426-12430 (1995).	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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